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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. HENRY DANIELL 922.6641P 09/251,638 02/17/1999 3456 **EXAMINER** 35811 7590 12/11/2006 IP GROUP OF DLA PIPER US LLP KUBELIK, ANNE R ONE LIBERTY PLACE ART UNIT PAPER NUMBER 1650 MARKET ST, SUITE 4900

1638

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		09/251,638	DANIELL, HENRY
		Examiner	Art Unit
	·	Anne R. Kubelik	1638
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
2a)	Responsive to communication(s) filed on 10/4/06. This action is FINAL. 2b) ☑ This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims			
4) Claim(s) 1.3-5.8.10 and 11 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1.3-5 and 10-11 is/are rejected. 7) Claim(s) 8 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
2) D Notice 3) D Inform	e(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other:	ate

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 October 2006 has been entered.

- 2. Claims 1, 3-5, 8 and 10-11 are pending.
- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4. The rejection of claims 1 and 8 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter) is withdrawn in light of Applicant's amendment of the claims.
- 5. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's cancellation of the claim.

Claim Rejections - 35 USC § 112

6. Claims 1, 3-5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains,

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or with which it is most nearly connected, to make and/or use the invention. The rejection is different from the rejection set forth in the Office action mailed 5 April 2006, as applied to claims 1, 3-5 and 8-12. Applicant's arguments filed 4 October 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to multitude of expression cassettes comprising a fiber specific promoter operably linked to a nucleic acid that comprises a synthetic coding sequence encoding GVGVP or VPGVG that is repeated at least once and to cotton plants comprising any of a multitude of nucleic acids that comprise a synthetic coding sequence encoding GVGVP or VPGVG that is repeated at least once.

The instant specification, however, only provides guidance for nucleic acids encoding GVGVPGVGFPGEGFPGVGVPGVGFPGFGFP, which comprises GVGVP twice (¶ 10.3) and (GVGVP)₁₂₀ (¶13-14) and prophetic expression of (GVGVP)₁₃₀ in cotton (¶15).

The specification teaches that the goal of the invention is to produce cotton fiber that has increased fiber strength, altered thermal and water absorption qualities, and enhanced elasticity and dye binding capacity (¶7). Thus, the nucleic acids transformed into the cotton plants must encode proteins that can impart these qualities to the fibers.

The specification, however, does not teach such nucleic acids other than GVGVPGVGFPGEGFPGVGVPGVGFPGFGFP, (GVGVP)₁₂₀ and (GVGVP)₁₃₀. Other proteins that comprise GVGVP or VPGVG are not taught in the specification.

Furthermore, proteins in which GVGVP or VPGVG are repeated at least once but in which the rest of the protein sequence are unrelated to GVGVP or VPGVG are unlikely to impart increased fiber strength, altered thermal and water absorption qualities, and enhanced elasticity

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and dye binding capacity to cotton fibers. The properties of biopolymers are dependent upon their ability to form filaments, which is dependent upon having many copies of the repeating units (Urry et al, 1996, Protein-based polymeric materials (synthesis and properties), In: Polymeric Materials Encyclopedia, Salamone, JC, ed., CRC Press, Boca Raton, pages 7263-7279; see paragraph spanning pg 7272-7273). Thus, proteins in which GVGVP or VPGVG are repeated only once are unlikely to confer increased fiber strength, altered thermal and water absorption qualities, and enhanced elasticity and dye binding capacity to cotton fibers.

Given the claim breath and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that comprise a synthetic coding sequence encoding GVGVP or VPGVG that is repeated at least once and cotton plants comprising them.

Applicant urges that their amendments have overcome the rejection (response pg 4).

This is not persuasive. The previous rejection has been withdrawn; however, it is replaced by the new rejection above.

7. Claims 1, 3-5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is different from the rejection set forth in the Office action mailed 5 April 2006, as applied to claims 1, 3-5 and 8-12. Applicant's arguments filed 4 October 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids encoding GVGVP or VPGVG that is repeated at least once. In contrast, the specification describes only a few nucleic

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acids encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The function that confers increased fiber strength, altered thermal and water absorption qualities, and enhanced elasticity and dye binding capacity to cotton fibers is not confers to the full scope of proteins in which GVGVP or VPGVG at least once; this property would be confers only to proteins in which GVGVP or VPGVG were repeated many times. The specification does not describe proteins with the ability to confer these properties to cotton fibers and in which GVGVP or VPGVG is repeated at least once but are not comprised of many repeats of GVGVP or VPGVG.

Hence, Applicant has not, in fact, described nucleic acids that comprise a synthetic coding sequence encoding GVGVP or VPGVG that is repeated at least once, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that their amendments have overcome the rejection (response pg 4).

This is not persuasive. The previous rejection has been withdrawn; however, it is replaced by the new rejection above.

8. Claims 1, 3-5,8 and 10-11 are free of the prior art, given the failure of the prior art to teach a cotton plant transformed with a gene or coding sequence that encodes a protein comprises GVGVP or VPGVG that is repeated at least once, wherein the gene or coding

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sequence does not occur in nature and given the failure of the prior art to teach an expression cassette for transformation of such plants, wherein the cassette comprises a fiber-specific promoter.

9. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D. December 1, 2006

ANNE KUBELIK, PH.D.

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